

PATENT

Lawn et al.

Filed: June 16, 2000

Examiner:

Group Art Unit:

Sir:

1. We are transmitting herewith the attached:

- Information Disclosure Statement (w/44) patents and references);
- PTO Form 1449; and
- Post Card

2. With respect to additional fees:

 x A. No additional fee is required.

 B. Attached is a check in the amount of \$0.00.

3. **General Authorization:** Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490. A duplicate copy of this sheet is enclosed.

4. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Asst. Commissioner for Patents, Washington, D.C. 20231 on this 18th day of September, 2000.

Dated: September 18, 2000

By :

Anita J. Terpstra
Reg. No. P47,132

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 99,395-B)

In the Application of: Lawn et al.)

Serial No.: 09/596,141)

Filing Date: June 16, 2000)

For: COMPOSITIONS AND)
METHODS FOR INCREASING)
CHOLESTEROL EFFLUX AND)
RAISING HDL USING ATP)
BINDING CASSETTE)
TRANSPORTER PROTEIN ABC1)



Examiner:

Group Art Unit:

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicants wish to make the following references listed on the enclosed Form PTO-1449 of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56.

Copies of the references cited on the Form PTO-1449 are enclosed.

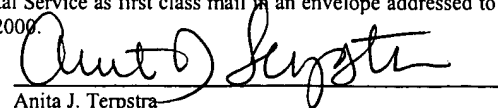
6,080,842 June 27, 2000 Hillman, et al.

5,858,719 January 12, 1999 Hillman, et al.

CERTIFICATE OF MAILING (37 C.F.R. 1.8a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington D.C. 20231, on September 18, 2000.

Date: September 18, 2000


Anita J. Terpstra

WO 00/34461 15 June 2000 PCT International

WO 00/18912 06 April 2000 PCT International

WO 99/31133 24 June 1999 PCT International

Babitt et al. 1999. "Murine SR-BI, a high density lipoprotein receptor that mediates selective lipid uptake, is N-glycosylated and fatty acylated and colocalizes with plasma membrane caveolae," J. Biol. Chem., 272: 13242-13249.

Becq et al. 1997. "ABC1, an ATP Binding Cassette Transporter Required for Phagocytosis of Apoptotic Cells, Generates a Regulated Anion Flux after Expression in *Xenopus laevis* Oocytes," J. Biol. Chem., 272: 2695-2699.

Bodzioch et al. 1999. "The gene encoding ATP-binding cassette transporter 1 is mutated in Tangier Disease," Nat. Genet., 22: 347-351.

Bojanovski et al. 1987. "In vivo metabolism of proapolipoprotein A-I in Tangier disease," J. Clin. Invest., 80: 1742-1747.

Borst et al. 2000. "ABC transporters in lipid transport," Biochim Biophys Acta, 1486(1):128-44.

Bowie et al. 1990. "Deciphering the message in protein sequences: tolerance to amino acid substitutions," Science, 247: 1306-1310.

Brooks-Wilson et al. 1999. "Mutations in ABC1 in Tangier disease and familial high-density lipoprotein deficiency," Nature Genetics, 22: 336-345.

Costet et al. 2000. "Sterol-dependent transactivation of the human ABC1 promoter by LXR/RXR," J. Biol. Chem., 275: 28240-28245.

Cunningham et al. 1989. "High-resolution epitope mapping of hGH-receptor interactions

by alanine-scanning mutagenesis," Science, 244: 1081-1085.

Dobeli et al. "Role of the carboxy-terminal sequence on the biological activity of human immune interferone (IFN-)," J. Biotechnology, 7: 199-216 (1988).

Francis et al. 1995. "Defective Removal of Cellular Cholesterol and Phospholipids by Apolipoprotein A-I in Tangier Disease," J. Clin. Invest., 96: 78-87.

Freeman, 1999. "Effluxed lipids: Tangier Island's latest export," Proc. Natl. Acad. Sci. USA, 96: 10950-10952.

Gura, T. 1999. "Gene Linked to Faulty Cholesterol Transport," Science, 285: 814-815.

Hayden et al. 2000. "Cholesterol efflux regulatory protein, Tangier disease and familial high-density lipoprotein deficiency," Curr. Opin. Lipidol., 11(2):117-22.

Hobbs et al. 1999. "ABC1:connecting yellow tonsils, neuropathy, and very low HDL," J. Clin. Invest., 104: 1015-1017.

Hokland et al. 1993. "Cyclic AMP Stimulates Efflux of Intracellular Sterol from Cholesterol-loaded Cells," J. Biol. Chem., 268: 25343-25349.

Langmann et al. 1999. "Molecular Cloning of the Human ATP-Binding Cassette Transporter 1 (hABC1): Evidence for Sterol-Dependent Regulation in Macrophages," Biochem. Biophys. Res. Comm., 257: 29-33.

Lawn et al. 1999. "The Tangier disease gene product ABC1 controls the cellular apolipoprotein-mediated lipid removal pathway," J. Clin. Invest., 104: R25-R31.

Lawn et al. 1992. "Atherogenesis in transgenic mice expressing human apolipoprotein(a)," Nature, 360: 670-672.

Luciani et al. 1994. "Cloning of Two Novel ABC Transporters Mapping on Human

Chromosome 9," Genomics, 21: 150-159.

Marcil et al. 1999. "Mutations in the ABC1 gene in familial HDL deficiency with defective cholesterol efflux," The Lancet, 354: 1341-1346.

Oram et al. 2000. "ABCA1 is the cAMP-Inducible Apolipoprotein Receptor that Mediates Cholesterol Secretion from Macrophages," JBC Papers in Press. Published on July 28, 2000 as Manuscript M006738200.

Oram et al. 2000. "ABCA1-mediated transport of cellular cholesterol and phospholipids to HDL apolipoproteins," Curr. Opin. Lipidol., 11(3): 253-60.

Oram et al. 1999. "Reduction in apolipoprotein-mediated removal of cellular lipids by immortalization of human fibroblasts and its reversion by cAMP: lack of effect with Tangier disease cells," J. Lipid Res., 40: 1769-1781.

Oram et al. 1996. "Apolipoprotein-mediated removal of cellular cholesterol and phospholipids," J. Lipid Res., 37: 2743-2491.

Ordovas, J. M. 2000. "ABC1: the gene for Tangier disease and beyond," Nutr. Rev., 58(3 Pt 1): 76-9.

Owen, J. 1999. "Role of ABC1 gene in cholesterol efflux and atheroprotection," The Lancet, 354: 1402-1403.

Panousis et al., 2000. "Interferon-gamma induces downregulation of Tangier disease gene (ATP-binding-cassette transporter 1) in macrophage-derived foam cells," Arterioscler. Thromb. Vasc. Biol., 20(6): 1565-71.

Pullinger, et al. 2000. "Analysis of hABC1 Gene 5' End: Additional Peptide Sequence, Promoter Region, and Four Polymorphisms," Biochem. Biophys. Res. Comm., 271: 451-455.

Remaley et al. 1999. "Human ATP-binding cassette transporter 1 (ABC1): Genomic organization and identification of the genetic defect in the original Tangier disease kindred," Proc. Natl. Acad. Sci. USA, 96: 12685-12690.

Ron et al. 1993. "Expression of biologically active recombinant keratinocyte growth factor. Structure/function analysis of amino-terminal truncation mutants," J. Biol. Chem., 268: 2984-2988.

Rust et al. 1999. "Tangier disease is caused by mutations in the gene encoding ATP-binding cassette transporter 1," Nat. Genet., 22: 352-355.

Rust et al. 1998. "Assignment of Tangier disease to chromosome 9q31 by a graphical linkage exclusion strategy," Nat. Genet., 20: 96-98.

Schwartz et al. 2000. "ABC1 Gene Expression and ApoA-I-mediated Cholesterol Efflux are regulated by LXR," Biochem. Biophys. Res. Commun. 274(3): 794-802.

Smith et al. 1996. "Cyclic AMP Induces Apolipoprotein E Binding Activity and Promotes Cholesterol Efflux from a Macrophage Cell Line to Apolipoprotein Acceptors," J. Biol. Chem., 271: 30647-30655.

Stangl et al. 1998. "Scavenger receptor, class B, type I-dependent stimulation of cholesterol esterification by high density lipoproteins, low density lipoproteins, and nonlipoprotein cholesterol," J. Biol. Chem., 273: 31002-31008.

Takahashi et al. 2000. "Identification of cAMP analogue inducible genes in RAW264 macrophages," Biochim. Biophys. Acta, 1492(2-3):385-394.

Tsujita et al. 2000. "Apolipoprotein-mediated cellular cholesterol/phospholipid efflux and plasma high density lipoprotein level in mice," Biochim Biophys Acta, 1485(2-3): 199-213.

Young et al. 1999. "The ABCs of cholesterol efflux," Nat. Genet., 22: 316-318.

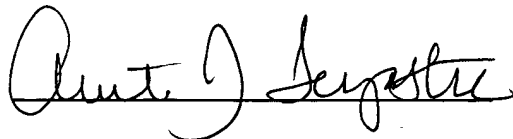
The Examiner is respectfully requested to consider the references in their entirety and to so indicate by initialing the appropriate box on the Form PTO-1449. By submission of the references on the Form PTO-1449, no representation is intended as to the relative importance of any portion of the references. Furthermore, such citation is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103. Applicants expressly reserve the right to establish that the aforesaid references are not prior art, and/or are not art that is analogous or relevant to the claimed invention.

This Information Disclosure Statement is being filed:

within three months of the date of filing or before the mailing date of a first Office Action on the merits, pursuant to 37 C.F.R. §1.97 (b).

Please charge any underpayment or credit any overpayment in connection with this communication to Deposit Account No. 13-2490. A duplicate copy of this communication is enclosed for this purpose.

Respectfully submitted,



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